IN THE DISTRICT COURT OF OKLAHOMA COUNTY
STATE OF OKLAHOMA

FILED IN DISTRICT COURT
OKLAHOMA COUNTY

AUG 27 2019

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TRACY HANDLEY; SHELLY PHILLIPS; MARGARET ADEBAYO; JANICE ATWELL; ERNEST HOPKINS; DARNELL NEWTON, BRETT RICH; And SANDEE SALMON, on behalf of themselves, and all others similarly situated,

Plaintiffs,

v.

DAIICHI SANKYO, INC.; DAIICHI SANKYO CO., LTD.; DAIICHI SANKYO US HOLDINGS, INC.; FOREST LABORATORIES, LLC; FOREST LABORATORIES, INC.; FOREST PHARMACEUTICALS, INC.; and FOREST RESEARCH INSTITUTE, INC.

Defendants.

CASE NO. CJ-2019-4772

CLASS ACTION PETITION

Plaintiffs, Tracey Handley, Shelly Phillips, Margaret Adebayo, Janice Atwell, Ernest Hopkins, Darnell Newton, Brett Rich, and Sandee Salmon, on behalf of themselves and all others similarly situated ("Plaintiffs"), who have taken the drug Omlesartan (also known as Benicar®, Benicar HCT®, Azor®, or Tribenzor®), who have suffered a personal injury, including injury to gastrointestinal tissue, as a result of the use of this medication, and who have not

participated in the global Benicar settlement with Daiichi Sanko announced on August 1, 2017 ("Global Settlement").

Plaintiffs originally filed this action on August 28, 2018 in Pottawatomie County. The case was subsequently removed to the Western District of Oklahoma and dismissed without prejudice on August 31, 2018. Plaintiffs hereby invoke the Oklahoma Savings Statute, 12 O.S. §100.

INTRODUCTION

1. This Petition sets forth facts and allegations common to those Plaintiffs whose claims relating to olmesartan medoxomil products ("olmesartan products") have been filed in this Class Action litigation. It includes allegations involving four different olmesartan products, including Benicar®, Benicar HCT®, Azor®, and Tribenzor®. All of these products were manufactured sold, distributed, and promoted by the Daiichi Sankyo Defendants, and three of the products, Benicar®, Benicar HCT®, and Azor®, were also promoted by the Forest Defendants (Daiichi Sankyo Defendants and Forest Defendants hereinafter collectively referred to as "Defendants"), as more fully set forth below. Plaintiffs seek compensatory and punitive damages, monetary restitution, and all other available remedies as a result of injuries caused by Defendants' defective olmesartan products. Plaintiffs claim and allege that their damages and injuries are a direct

and proximate result of Defendants' negligent, intentional, and wrongful acts, omissions, and conduct regarding Defendants' design, development, formulation, manufacture, testing, packaging, labeling, promotion, advertising, marketing, distribution and sale of products containing the drug olmesartan medoxomil.

2. Plaintiffs herein, by and through Plaintiffs' attorneys, bring this action for personal injuries and/or wrongful death suffered by the Injured Party (the "Injured Party" and collectively the Injured Party and/or Plaintiffs are the "Plaintiff(s)"), as detailed more fully herein, as a proximate result of the Plaintiffs being prescribed and ingesting the defective and unreasonably dangerous prescription olmesartan medoxomil drug products including, Benicar®, Benicar HCT®, Azor®, and Tribenzor®. Defendants promoted Benicar®, Benicar HCT®, Azor®, and Tribenzor®, as safe and effective for the treatment or prophylaxis of hypertension and other medical conditions, including renal disease, on information and belief. Defendants and/or their predecessors in interest knew or should have known that use of olmesartan medoxomil products increased the risk of developing multiple injuries, including serious gastrointestinal injuries, such as Olmesartan Associated Enteropathy ("OAE"), sprue-like enteropathy, villous atrophy/blunting/damage, inflammation, nausea, vomiting, chronic diarrhea, malnutrition, dehydration, atrophy, kidney failure, weight loss, abdominal and gastrointestinal pain, colitis, and/ or gastritis; and that the labels and sales and

marketing documents for Benicar®, Benicar HCT®, Azor®, and Tribenzor®, failed to include such risks and misrepresented the safety of the drugs, and continue to inadequately and inaccurately disclose those risks today. This Petition is intended to serve the administrative functions of efficiency and economy by presenting certain common claims and common questions of fact and law for consideration by this Court within the context of this class action proceeding.

3. Plaintiffs in these actions seek compensation for injuries resulting from use of defective prescription olmesartan products manufactured, sold, distributed and promoted by Defendants. The injuries resulting from their use of olmesartan products, include, but are not limited to, serious gastrointestinal injuries, Olmesartan Associated Enteropathy ("OAE"), sprue-like enteropathy, villous atrophy/blunting/damage, inflammation, nausea, vomiting, chronic diarrhea, malnutrition, dehydration, atrophy, kidney failure, weight loss, abdominal and gastrointestinal pain, colitis, gastritis, and including permanent injuries resulting therefrom, and death (hereinafter referred to as "Plaintiffs' injuries" or "injuries" throughout this Petition).

4. The four olmesartan products at issue in this litigation are: Benicar®, Benicar HCT®, Azor®, and Tribenzor®. With respect to each of these products, Defendants exaggerated their benefits and understated, omitted and/or failed to

adequately warn patients and physicians about the risks associated with such products.

5. The injuries and damages to Plaintiffs were caused by the unreasonably dangerous conditions of the above named olmesartan products and Defendants' wrongful acts and omissions.

6. At all times herein mentioned, Defendants were engaged in the business of, or were successors-in-interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, labeling, promoting, packaging and/or advertising for sale or selling the olmesartan products, Benicar®, Benicar HCT®, Azor®, and Tribenzor®.

7. At all times herein mentioned, Defendants were authorized to do or otherwise engaged in business within the State of Oklahoma and elsewhere and did in fact supply the aforementioned products within the State of Oklahoma and elsewhere, including Plaintiffs' states of residence and ingestion.

8. At all times herein mentioned, the officers and directors of Defendants authorized and directed the production and promotion of olmesartan products, namely, Benicar®, Benicar HCT®, Azor®, and Tribenzor® when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of these olmesartan products, and the failure to adequately instruct and warn thereof, and thereby actively participated in the tortious conduct

which resulted in the physical injuries and/or wrongful death as described herein.

JURISDICTION AND VENUE

9. Plaintiffs claim an amount in controversy not exceeding $5,000,000 with damages to be determined by jury trial.

10. Venue is proper in this Court, as the cause of action partially arose in the State of Oklahoma.

11. Plaintiffs' claims in this action are brought under Oklahoma law. Plaintiffs do not herein bring, assert, or allege, either expressly or impliedly, any causes of action arising under any federal law, statute, regulation, or provision. Thus, there is no federal jurisdiction in this action on the basis of a federal question. Furthermore, federal diversity jurisdiction is lacking in this action.

12. Principal injuries resulting from the alleged conduct or any related conduct of each Defendant were incurred in Oklahoma. 28 U.S.C. § 1332 (d)(4)(A) & (B).

13. The Court has personal jurisdiction over all parties.

PLAINTIFFS/INJURED PARTIES GENERALLY

14. This Petition is filed on behalf of all Individual Injured Plaintiffs and/or Injured Parties whose claims are included herein and who did not participate in the Global Settlement. Tracey Handley and Shelly Phillips are citizens of Oklahoma, and Plaintiffs Margaret Adebayo, Janice Atwell, Ernest Hopkins, Darnell Newton, Brett Rich, and Sandee Salmon ("Plaintiffs"), in this class action

have all suffered personal injuries as a result of use of olmesartan products. In addition, and where applicable, this Petition is also filed on behalf of Plaintiffs' spouses, children, parents, decedents, estates, wards and/or heirs, all as represented by Plaintiffs' counsel.

15. Plaintiffs have suffered personal injuries as a direct and proximate result of Defendants' conduct and misconduct as described herein and in connection with, inter alia, the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of the olmesartan products.

16. Plaintiffs have suffered personal injuries as a direct and proximate result of Defendants' conduct and misconduct as described herein and in connection with, inter alia, the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of the olmesartan products.

17. As a direct result of the ingestion of Defendants' olmesartan products, Plaintiffs developed serious injuries and consequent physiological damage caused by the ingestion of these drugs. The physical injuries suffered by Plaintiffs include, but are not limited to, serious gastrointestinal injuries, Olmesartan Associated Enteropathy ("OAE"), sprue-like enteropathy, villous atrophy/blunting/damage, inflammation, nausea, vomiting, chronic diarrhea,

malnutrition, dehydration, atrophy, kidney failure, weight loss, abdominal and gastrointestinal pain, colitis, gastritis, and including permanent injuries resulting therefrom, and death. Plaintiffs' injuries are serious, longstanding, and permanent, resulting in multiple hospitalizations and even death in some cases. Had Plaintiffs or Plaintiffs' health care professional(s) been properly warned by Defendants regarding the risks from ingesting Defendants' olmesartan products, the Plaintiffs would not have ingested these drugs and/or would have ceased use of the olmesartan products.

18. As a direct and proximate result of the unreasonably dangerous condition of Defendants' *olmesartan* products and Defendants' acts and omissions, Plaintiffs suffered the injuries described herein. Plaintiffs accordingly seek damages associated with these injuries, including, but not limited to damages for severe mental and/or physical pain and suffering along with economic loss.

19. Plaintiffs file these lawsuits within the applicable limitations period. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiffs' injuries as their cause was unknown to Plaintiffs. Plaintiffs did not suspect, nor did Plaintiffs have reason to suspect, that Plaintiffs had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, prior to the applicable limitations period. Additionally, Plaintiffs were prevented from discovering this information

sooner because Defendants misrepresented and continue to misrepresent to the public and to health care professional(s) that *olmesartan* products are safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiffs to discover potential causes of action. For example, and not by way of limitation, Defendants did not adequately warn of the gastrointestinal and related side effects and sequelae beginning with the first marketing of the *olmesartan* products, and failed to affirmatively notify the medical and patient communities of the full scope of risks known to be associated with and caused by the *olmesartan* products, from initial marketing to the present.

DEFENDANTS

20. Defendants named in this action include Daiichi Sankyo, Inc., Daiichi Sankyo Co., Ltd., Daiichi Sankyo US Holdings, Inc. (collectively referred to as "Daiichi Sankyo Defendants"), Forest Laboratories, LLC, Forest Laboratories, Inc., Forest Pharmaceuticals, Inc., and Forest Research Institute, Inc. (collectively referred to as "Forest").

A. Daiichi Sankyo Defendants

21. On information and belief, Defendant Daiichi Sankyo, Inc. ("Daiichi Sankyo U.S.") is a corporation organized and existing under the laws of the State of Delaware, with its principle place of business located at Two Hilton

Court, Parsippany, New Jersey 07054.

22. On information and belief, Daiichi Sankyo U.S. is or was also known as Sankyo USA Development, Sankyo Pharma Development, Sankyo Pharma Inc., Daiichi Sankyo Pharma Development, Daiichi Pharmaceuticals, Inc., Daiichi Medical Research, Inc., and Daiichi Pharma Holdings, Inc.

23. On information and belief, Daiichi Sankyo U.S. is in the business of designing, marketing, researching, distributing, packaging, marketing, promoting and selling pharmaceutical drugs, including those used by Plaintiffs, across the United States, including within the State of Oklahoma.

24. On information and belief, Daiichi Sankyo U.S. has a development and regulatory group named Daiichi Sankyo Pharma Development with offices in Edison, NJ, and a research institute named Daiichi Sankyo Research Institute with offices in Edison, NJ.

25. On information and belief, Defendant Daiichi Sankyo U.S. Holdings, Inc. is a Delaware corporation with its principle place of business located at Two Hilton Court, Parsippany, New Jersey 07054.

26. On information and belief, Daiichi Sankyo U.S. is a wholly owned subsidiary of Daiichi Sankyo U.S. Holdings, Inc.

27. On information and belief, Daiichi Sankyo U.S. Holdings, Inc. operates as a holding company for Daiichi Sankyo Co., Ltd.

28. On information and belief, Defendant Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo Japan") is and was at all relevant times a corporation organized and existing under the laws of Japan, having a principal place of business at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan.

29. On information and belief, Daiichi Sankyo Japan is in the business of designing and manufacturing prescription drugs, including those used by Plaintiffs, across the world, including in the United States and specifically within the State of Oklahoma.

30. On information and belief, Daiichi Sankyo Japan was formed by a merger between Daiichi Pharmaceutical Company, Ltd., and Sankyo Company, Ltd.

31. On information and belief, Daiichi Sankyo Japan is or was the parent company of Daiichi Sankyo U.S. and/or Daiichi Sankyo U.S. Holdings, Inc., and exercised control over both entities at all times relevant hereto. On information and belief, the agreements between and among the Daiichi defendants, and their affiliates, and subsidiaries, provides for Daiichi Sankyo Japan to have ultimate control over all relevant decisions, policies, and conduct, and therefore is liable for any and all tort liabilities of Defendants Daiichi Sankyo U.S. and/or Daiichi Sankyo U.S. Holdings, Inc.

32. On information and belief, Daiichi Sankyo U.S. operates as the U.S. headquarters of Daiichi Sankyo Japan. At least four of the principals, members,

directors, or officers of Daiichi Sankyo U.S. are also members of Daiichi Sankyo Japan. In addition, Daiichi Sankyo Japan operates several research and development facilities across the world, including collaborating with Daiichi Sankyo U.S. to oversee global clinical trials from its headquarters in Edison, New Jersey.

33. There existed, at all relevant times to this action, a unity of interest in ownership between Daiichi Sankyo Japan and Daiichi Sankyo U.S., such that any independence from, and/or separation between and among the Defendants has ceased and/or never existed; and each of them are the alter egos of one another. The two Defendants Daiichi Sankyo Japan and Daiichi Sankyo U.S., and each of them, condoned and ratified the negligent, willful, intentional, and wrongful acts, omissions, and conduct of each other.

34. For convenience purposes, Defendants Daiichi Sankyo Japan, Daiichi Sankyo U.S., and Daiichi Sankyo U.S. Holdings, Inc., are hereinafter collectively referred to as "Daiichi Sankyo."

35. On information and belief, Daiichi Sankyo designs and manufactures numerous pharmaceutical drugs for sale and use throughout the United States, including within the State of Oklahoma.

36. On information and belief, Daiichi Sankyo designed, manufactured, packaged, labeled, distributed, sold, marketed, advertised, and/or promoted

the blood pressure drugs containing *olmesartan medoxomil*, including those used by Plaintiffs, which are marketed in the United States as Benicar®, Benicar HCT®, Azor®, and Tribenzor®. Daiichi Sankyo refers to these drugs collectively as the "Benicar Family."

B. Forest Defendants

37. On information and belief, Forest Laboratories, LLC ("Forest Labs"), formerly known as Forest Laboratories, Inc., is a Delaware limited liability company having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054. Forest Labs is in the business of manufacturing, distributing, marketing, and promoting numerous pharmaceutical drugs for sale and use throughout the United States, including within the State of Oklahoma.

38. On information and belief, Defendant Forest Laboratories, Inc., prior to becoming Forest Laboratories, LLC, was a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022. Forest Laboratories, Inc. was in the business of manufacturing, distributing, marketing and promoting numerous pharmaceutical drugs for sale and use throughout the United States, including within the State of Oklahoma.

39. On information and belief, Defendant Forest Pharmaceuticals, Inc. ("Forest Pharmaceuticals") is incorporated in Delaware with its principal place

of business located at 13600 Shoreline Drive, St. Louis, Missouri. At all times relevant to this action, Defendant Forest Pharmaceuticals is and has been a division and wholly owned subsidiary of Forest Labs responsible for the manufacture, distribution, and sale of prescription medication for Forest Labs. Forest Pharmaceuticals has at least eight offices in New York and regularly transacts business within the State of Oklahoma.

40. On information and belief, Forest Research Institute, Inc. ("FRI"), is a wholly-owned subsidiary of Forest Laboratories, Inc., and was and still is a corporation duly existing under virtue of the laws of the State of Oklahoma with its principal place of business at Harborside Financial Center, Plaza V, Suite 1900, Jersey City, New Jersey. At all times hereinafter mentioned, Defendant FRI was and still is pharmaceutical entity involve in research, development, testing, manufacture, production, promotion, distribution and marketing of pharmaceuticals for distribution, sale and use by the general public of pharmaceutical medication, including the *olmesartan* products, Benicar®, Benicar HCT®, and Azor® throughout the United States.

41. There existed, at all relevant times to this action, a unity of interest in ownership between Forest Labs, Forest Laboratories, Inc., Forest Pharmaceuticals, and FRI, such that any independence from, and/or separation between and among the Defendants has ceased and/or never existed; in that these

four Defendants, and each of them are the alter egos of one another. The four Defendants, and each of them, condoned and ratified the negligent, willful, intentional, and wrongful acts, omissions, and conduct of each other.

42. For convenience purposes, Defendants Forest Labs, Forest Laboratories, Inc., Forest Pharmaceuticals and FRI are hereinafter referred collectively as "Forest."

43. On information and belief, Defendants Forest and Daiichi Sankyo entered an expense and profit sharing relationship in exchange for the co-promotion of blood pressure drugs containing *olmesartan medoxomil*, including but not limited to Benicar®, Benicar HCT®, and Azor®, which Plaintiffs used.

44. On information and belief, the Daiichi Defendants entered into a co-promotion agreement with Forest in 2002 for the co-promotion of Benicar® and Benicar HCT®. The Benicar® co-promotion agreement was extended to May 31, 2008. Upon information and belief, although Forest's co-promotion activities may have ceased on or about May 31, 2008, Forest continued to receive Benicar® and Benicar HCT® profits until at least March 31, 2014.

45. On information and belief, Daiichi Sankyo and Forest entered into an additional co-promotion agreement for the co-promotion of Azor® on or about August 21, 2007. The Azor® co-promotion agreement remained in effect until approximately June 30, 2008.

46. On information and belief, Forest profited from the sale of the *olmesartan* products which it marketed to Plaintiffs and their prescribing healthcare providers, receiving forty-five (45) percent of Benicar®, Benicar HCT®, and Azor® profits in exchange for its co-promotion of the products.

C. All Defendants

47. The term "Defendants" is used hereafter to refer to all the entities identified above.

48. Defendants are corporations organized under the laws of various states of the United States of America or the Dominion of Japan that were or are doing business within the State of Oklahoma. The aforementioned Defendants designed, marketed, sold, distributed, packaged, promoted, labeled, researched, tested or manufactured the *olmesartan medoxomil* product(s) which Plaintiffs ingested.

49. At all times relevant to this action, all Defendants and each of them were in the capacity of the principal or agent of all of the other Defendants, and each of them, and acted within the scope of their principal and agent relationships in undertaking their actions, conduct, and omissions alleged in this Complaint. All Defendants, and each of them, acted together in concert or aided and abetted each other and conspired to engage in the common course of misconduct alleged herein for the purpose of reaping substantial monetary profits from the sale of the *olmesartan medoxomil* products and for the purpose of enriching themselves

financially to the serious detriment of Plaintiffs' health and well-being.

50. At all times herein mentioned, Defendants, in interstate commerce and in this judicial district, advertised, promoted, supplied and sold to distributors and retailers for resale to health care professionals, hospitals, medical practitioners and the general public *olmesartan* products.

FACTS AND ALLEGATIONS

51. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

Olmesartan Products

52. On information and belief, Daiichi Sankyo Japan is the owner of the United States Letters Patent No. 5,616,599 ("the '599 patent"). The '599 patent claims various chemical compounds including *olmesartan medoxomil* specifically, as well as pharmaceutical compositions containing these compounds, and method for the treatment or prophylaxis of hypertension.

53. *Olmesartan medoxomil* is classified as an angiotension II receptor blocker ("ARB") and was the seventh commercialized ARB monotherapy product brought to the market.

54. On information and belief, the '599 patent was assigned by the inventors to Daiichi Sankyo Japan and remains assigned to Daiichi Sankyo Japan.

55. Daiichi Sankyo U.S. is a licensee under the '599 patent and is marketing

and selling pharmaceutical drugs containing *olmesartan medoxomil* that are manufactured by Daiichi Sankyo Japan throughout the United States, including within the State of Oklahoma.

56. On information and belief, Daiichi Sankyo U.S. holds an approved new drug application ("NDA") No. 21-286 for Benicar® tablets (5 mg, 20 mg, and 40 mg), which tablets contain the active ingredient *olmesartan medoxomil.* Benicar® tablets were approved by the United Stated Food and Drug Administration ("FDA") on April 25, 2002, for treatment of hypertension.

57. On information and belief, Daiichi Sankyo U.S. holds an approved NDA No. 21-532 for Benicar HCT® tablets (40/12.5 mg, 40/25 mg, and 20/12.5 mg), which tablets contain the active ingredients *olmesartan medoxomil* and *hydrochlorothiazide.* Benicar HCT® tablets were approved by the FDA on June 5, 2003, for the treatment of hypertension, but are not indicated for initial therapy.

58. On information and belief, Daiichi Sankyo U.S. holds an approved NDA No. 22-100 for Azor® tablets (5/20 mg, 5/40 mg, 10/20 mg, and 10/40 mg), which tablets contain the active ingredients *amlodipine besylate* and *olmesartan medoxomil.* Azor® tablets were approved by the FDA on September 26, 2007 for the treatment of hypertension, alone or in combination with other antihypertensive agents.

59. On information and belief, Daiichi Sankyo U.S. holds an approved NDA No. 20-0175 for Tribenzor® tablets (40/10/25 mg, 40/5/12.5 mg, 20/5/12.5 mg, 40/5/25 mg, 40/10/12.5 mg), which tablets contain the active ingredients *olmesartan medoxomil*, *amlodipine* and *hydrochlorothiazide*. Tribenzor® tablets were approved by the FDA on July 23, 2010, for treatment of hypertension, but are not indicated for initial therapy.

60. The terms "Benicar" and "*olmesartan*" are frequently and interchangeably employed, in common usage among the medical community, to refer to all or any of the *olmesartan medoxomil* products, including the specific U.S. brand name products Benicar®, Benicar HCT®, Azor®, and Tribenzor®.

61. On information and belief, Daiichi Sankyo is or was referring to its *olmesartan medoxomil* products as the "Benicar Family."

62. As required by law for all prescription drug products, each of the Defendants include the product's "labeling," also called "package inserts," placed on or in the packages from which the products were to be dispensed from pharmacies, or from which "product samples," if any, were to be dispensed by doctors. The labeling includes information on the product's active and inactive ingredients, clinical pharmacology, "indications" and usage, contraindications, warnings, precautions, and side effects (adverse reactions

and overdosage). Defendants also utilized sales and marketing literature and advertising, including on the internet, to provide product related information, and to promote the *olmesartan* products.

63. The "indications" or "indicated" uses for the *olmesartan* products, as reflected in the product labeling, include the treatment of hypertension, alone or with other antihypertensive agents, to lower blood pressure.

64. The text of the "indications" or "indicated" uses for the *olmesartan* products, did not adequately disclose the risks associated with use of the drugs.

65. The package inserts for the *olmesartan* products are materially identical to the prescribing information for the *olmesartan* products published in the Physician's Desk Reference.

66. In connection with all of the *olmesartan* products, Plaintiffs allege the following:

FDA Drug Safety Communication and Label Change

67. On July 3, 2013, the FDA issued a Drug Safety Communication warning that the blood pressure drug *olmesartan medoxomil*, marketed as Benicar®, Benicar HCT®, Azor®, and Tribenzor®, can cause intestinal problems known as sprue-like enteropathy. The FDA approved changes to the label of these drugs to include this concern. Some of the findings of the FDA include but are not limited to:

a. Symptoms of sprue-like enteropathy include severe, chronic diarrhea with substantial weight loss.

b. The enteropathy may develop months to years after starting *olmesartan medoxomil*, and sometimes require hospitalization.

c. If patients taking *olmesartan* develop these symptoms and no other cause is found, the drug should be discontinued, and therapy with another antihypertensive started.

d. Discontinuation of *olmesartan* has resulted in clinical improvement of sprue-like enteropathy symptoms in all patients.

e. Sprue-like enteropathy has not been detected with ARB drugs other than *olmesartan*.

f. In 2012, a total of approximately 1.9 million patients received a dispensed prescription for *olmesartan*-containing products from U.S. outpatient retail pharmacies.

g. The FDA identified 23 serious cases in the FAERS presenting as late onset diarrhea with significant weight loss and, in some cases, with intestinal villous atrophy on biopsy. All patients improved clinically after discontinuation of *olmesartan* medoxomil, and a positive rechallenge was seen in 10 of the cases.

h. In June 2012, Mayo Clinic researchers published a case series of sprue-like enteropathy associated with *olmesartan* in 22 patients whose clinical presentation was similar to that of the FAERS cases.

i. In May 2013, an article describing patients with villous atrophy and negative serologies for celiac disease reported that some patients without definitive etiologies from villous atrophy were characterized as having unclassified sprue. Some of these patients were subsequently found to have villous atrophy associated with *olmesartan* use

j. The FDA further investigated the signal of sprue-like enteropathy with *olmesartan* for a possible ARB class effect using active surveillance data. The FDA found that *olmesartan* users had a higher rate of celiac disease diagnoses in claims and administrative data than users of other ARBs. Interpretation is limited by the small number of events observed

at longer exposure periods and the uncertainty about the validity of codes for celiac disease, but these results support other data in suggesting a lack of a class effect.

k. Findings of lymphocytic or collagenous colitis and high association with HLA-DQ2/8 suggest a localized delayed hypersensitivity or cell-mediated immune response to *olmesartan* medoxomil.

68. The Defendants knew, or by the reasonable and careful employment of known scientific methods should have known, and, in the exercise of reasonable care toward patients who would be expected to ingest the *olmesartan* products, should have known, *inter alia*, that:

a. Studies published in peer-reviewed scientific and medical literature found there may be an association between *olmesartan* and Plaintiffs injuries;

b. These studies represent some of the best scientific evidence available for evaluating the association between *olmesartan* and Plaintiffs' injuries;

c. Physicians commonly prescribe *olmesartan* as treatment for hypertension for prolonged periods of six months to a year or more;

d. Clinical trials for the *olmesartan* drug only lasted up to three months in duration;

e. *Olmesartan*-Associated Enteropathy symptoms are typically and often experienced chronically over long periods of time; and/or

f. Clinical trials over periods greater than three months would demonstrate the effects of longer term cumulative exposure to *olmesartan*.

Existence of Post-Approval Data and Studies Further Supports a Causal Association Between the use of *Olmesartan* Products and Plaintiffs' Injuries

69. The existence of additional data, studies, and reports of adverse events published around the time of, and after, the FDA required label change in 2013,

further supports a causal association between the use of *olmesartan* products and Plaintiffs' injuries. These include, among other data, the following:

a. A case report out of the University of Pittsburgh documented a patient who suffered a twenty-five pound weight loss as a result of his chronic diarrhea. He did not respond to a gluten free diet, or to antibiotics, however when the olmesartan product was stopped, his symptoms began to improve. The authors concluded that they had "a very unique case describing an association of a severe form of spruelike enteropathy and olmesartan." S.E. Dreifuss, Y. Tomizawa,N.J. Farber, et al., Spruelike Enteropathy Associated with Olmesartan: An Unusual Case of Severe Diarrhea. Case Reports in Gastrointestinal Medicine. Epub ahead of print, accepted 20 February 2013.

b. A group of 16 patients with villous atrophy on biopsy, but with negative celiac serology, were examined by a group of physicians from Columbia University Medical Center. Of those 16 patients, all had positive dechallenges. One patient was given the *olmesartan* product again, and had a positive rechallenge. M. DeGaetani, C.A. Tennyson, et al. *Villous Atrophy and Negative Celiac Serology: A Diagnostic and Therapeutic Dilemma.* Am. J. Gastroenterol. 2013 May; 108(5): 647-53.

c. An October 2013 case report described a patient with a twenty-pound weight loss in just three weeks, whose symptoms began to resolve after the *olmesartan* product was no longer administered. The authors said, "we report a clear case of an angiotensin II inhibitor [Olmesartan] that caused villous blunting of the duodenum and gastrointestinal symptoms similar to those of celiac disease." J.A. Nielsen, A. Steephen, M. Lewin. *Angiotensin-II inhibitor (olmesartan)-induced collagenous sprue with resolution following discontinuation of drug.* World J. Gastroenterol. 2013 Oct 28; 19(40): 6928-30.

d. In a letter to the editor published in the November/December 2013 edition of the Journal of Clinical Gastroenterology, a group of physicians from The Ohio State University Wexner Medical Center in

Columbus described a case of *olmesartan* induced injury. They reported a patient who had been hospitalized for more than 15 days, had been put on total-parenteral nutrition, and who had evidence of villous atrophy of both the duodenum and jejunum on biopsy. When the *olmesartan* product was stopped, their symptoms began to resolve. The authors concluded that the case "illustrates an association between *olmesartan*...and a sprue-like enteropathy." P.P. Stanich, M. Yearsley, M.M. Meyer. *Olmesartan-associated Sprue-like Enteropathy*. J. Clin. Gastroenterol. 2013 Nov/Dec; 47(10): 894-5.

e. A group out of France published a case series in early 2014 which reported on five cases of *olmesartan* induced injury. The five cases were all recorded in a small gastroenterology unit in France. Four of the five cases had a small bowel biopsy showing villous atrophy, although the fifth patient's biopsy was normal. All five had positive dechallenge results, and two patients underwent rechallenge, one patient was actually rechallenged twice. The patients' symptoms returned with each reintroduction of the *olmesartan* product. The authors concluded that the rechallenge data argued strongly in favor of *olmesartan* being responsible, and also that "this ADR may not be as rare as it may first appear." H. Theophile, X.R. David, et al. *Five cases of sprue-like enteropathy in patients treated by olmesartan*. Dig. Liver Dis. 2014 Jan 25. Epub ahead of print.

f. Another January 2014 case report documented a woman who suffered from a forty-fivepound weight loss and twenty bowel movements a day, for a year. She presented to the hospital with a colon perforation. After the *olmesartan* product was withdrawn, her symptoms began to improve. M. Abdelghany, L. Gonzalez, et al. *Olmesartan Associated Sprue-like Enteropathy and Colon Perforation*. Case Reports in Gastrointestinal Medicine. Epub ahead of print, accepted 29 January 2014.

g. A literature review published in Alimentary Pharmacology and Therapeutics in 2014 reviewed 11 publications and 54 patients, including three additional patients diagnosed by the authors. The literature review revealed that the mean duration of *olmesartan* use was 3.3 years, duodenal villous atrophy was present in nearly all of the

reported cases, and increased intra-epithelial lymphocytes were in nearly two-thirds of the cases. All of the cases showed improvement upon discontinuation of the *olmesartan* product. The authors concluded that "*olmesartan*-associated sprue-like enteropathy may be considered as a distinct clinical entity, and should be included in the differential diagnosis of seronegative villous atrophy." G. Ianiro, S. Bibb, et al. *Systematic Review: Sprue-Like Enteropathy Associated with Olmesartan.* Ailment. Pharmacol. Ther. 2014; 40: 16-23.

h. A May 2014 literature review in the Journal of Pharmacy Practice found "a growing body of evidence supporting the association between *olmesartan* medoxomil and sprue-like enteropathy." M.L. Sanford and A.K. Nagel, *A Review of Current Evidence of Olmesartan Medoxomil Mimicking Symptoms of Celiac Disease.* J. Pharm. Prac. 1-4 (2014).

i. An abstract of an epidemiological study from France provides the strongest causation evidence in the published literature to date. The study examined the risk of severe intestinal malabsorption associated with *olmesartan*, compared to other ARBs and ACE inhibitors. The authors found that "*olmesartan* was associated with an increased risk of severe intestinal malabsorption. The increased risk appears after one year of treatment and reaches 9.53 after 2 years of olmesartan. ARBs other than *olmesartan* were not associated with an increased risk of severe intestinal malabsorption." M. Basson, M. Mezzarobba,et al. *Severe Malabsorption Associated with Olmesartan: A French Nationwide Cohort Study.* (Abstract only.)

j. A Nationwide survey of French gastroenterologists found striking evidence that *olmesartan* "causes a severe and immune-mediated enteropathy, with or without villous atrophy." The study also noted that "ARBs other than *olmesartan* were not associated with an increased risk of severe intestinal malabsorption." In addition to confirming the association, the study also noted the likely causal connection between *olmesartan* and patients "with severe clinical enteropathies *without* villous atrophy." (Emphasis added.) L. Marthey, G. Cadiot, et al. *Olmesartan-associated Enteropathy: Results of a National Survey.*

Ailment. Pharmacol. Ther. (Aug. 2014).

k. A review of case reports was published in the Pharmacovigilance Forum in January 2014. This review noted that "an association between *olmesartan* and sprue-like enteropathy has been observed in several case series and reports," but that "further clinical investigation is required to evaluate the specific mechanism of *olmesartan*- associated enteropathy," and suggested the benefits that could result from "[g]reater awareness of *olmesartan*-induced sprue-like enteropathy." T.H. Tran and H. Li, *Olmesartan and Drug-Induced Enteropathy*. Pharmacovig. Forum, Vol. 39 No. 1 (Jan. 2014).

l. An October 2014 case report documented seven patients suffering from diarrhea and weight loss. Three had to be hospitalized due to severe dehydration, electrolyte imbalance, and acute renal failure. All had villous atrophy on biopsy and all showed improvement when the *olmesartan* product was withdrawn. The authors noted that the "presence of a robust clinical response on suspension of the drug in all the patients gives strong support to its causality." N. Bhat, N.K. Anupama et al. Olmesartan-related sprue-like enteropathy. Indian J. Gastroenterol. Oct. 2014.

m. A case report in the Internal Medicine Journal in July 2014 described a patient who had symptom manifestation within six months of beginning *olmesartan*. Duodenal biopsies showed villous atrophy and intraepithelial lymphocytosis. When a gluten free diet failed to elicit any response, *olmesartan* was discontinued and the symptoms abated. N. Heerasing, Olmesartan-induced Enteropathy, Internal Medicine Journal, July 2014.

n. Annals of Pharmacotherapy published a case series documenting a patient's thirty-five-pound weight loss, dehydration, and kidney failure. Diagnostic tests revealed "pan-gastrointestinal enteropathy." Megan E. Hartranft, PharmD, and Randolph E. Regal, PharmD. "Triple Phase" Budesonide Capsules for the Treatment of Olmesartan- Induced Enteropathy. Annals of Pharmaco. 2014, Vol. 48(9) 1234- 1237.

o. Another case report of injuries extending beyond the duodenum was published in Endoscopy in 2014. That report was of a patient who had been hospitalized numerous times, incorrectly diagnosed with celiac, and had lost thirty pounds. Diagnostic testing showed villous atrophy of both the duodenum and the jejunum. Upon cessation of the *olmesartan* product, the symptoms began to abate. A. S. Khan, S. Peter, et al. Olmesartan-induced Enteropathy Resembling Celiac Disease. Endoscopy 2014: 46: E97-E98.

p. An Italian case report was also published in 2014, it documented a patient's twenty-two-pound weight loss and reliance upon total parenteral nutrition. The pathology showed villous atrophy of the duodenum, but also lymphocytic gastritis and colitis. G. Fiorucci, E. Pexeddu et al. Severe Spruelike Enteropathy due to Olmesartan. Rev. Esp. Enferm. Dig. Vol. 106, No. 2, pp 142-144 (2014).

70. Despite this mounting evidence and the growing number of adverse event reports, both formal and informal, Defendants have, to this day, failed to adequately and accurately inform Plaintiffs, healthcare providers, and the general public of the existence of a causal association between the use of *olmesartan* products and Plaintiffs' injuries.

Defendants' False and Misleading Advertising and Omissions and Minimization of Risk Information

71. On information and belief, Daiichi Sankyo spent $1 billion dollars in "promotional spending" between 2002 and 2008 for Benicar® and Benicar HCT®.

72. At all times relevant to this action, Daiichi Sankyo's *olmesartan* products

were the third highest selling Angiotensin II Receptor Blocker ("ARB") products available on the U.S. market.

73. The U.S. market for hypertension treatment is massive. Approximately 73 million people in the United States age 20 and older have hypertension, about sixty-one (61) percent of which (or 45 million) are under treatment.

74. On information and belief, Daiichi Sankyo invested heavily in face-to-face meetings with physicians, physician meeting events, and clinical samples to promote its *olmesartan* products.

75. On information and belief, Benicar®, Benicar HCT® and Azor® were sold as part of a co-promotion agreement with Forest, a recognized United States pharmaceutical company.

76. On information and belief, the Defendants launched in 2002 an aggressive marketing campaign focused on convincing physicians, including Plaintiffs' physicians, that Benicar® was the "ARB with superior efficacy and more."

77. On information and belief, Daiichi Sankyo and Forest distributed marketing materials to physicians, including Plaintiffs' physicians, and consumers claiming that its *olmesartan* products were superior, more effective, and safer than other antihypertensive drug products available.

78. In 2006, the FDA found Daiichi Sankyo and Forest's efficacy and safety

claims unsubstantiated and false or misleading. According to the FDA and contrary to Daiichi Sankyo's marketing claims, there was no evidence that Benicar was superior to, safer than, or more effective than other ARBs. The FDA also found that Daiichi Sankyo and Forest's marketing materials failed to include risk information necessary to qualify its safety and effectiveness claims presented for Benicar® and Benicar HCT®. In addition to omitting important risks from the patient information, the materials also minimized the risks it did present and misleadingly signaled to the reader that the risks that were presented are minimal in nature.

79. The FDA ordered Daiichi Sankyo and Forest to cease making these superiority and efficacy claims and to take corrective measures. The corrective measures included discontinuing use of approximately fifty promotional pieces dated all the way to 2002 and disseminating corrective messages to physicians who received the materials.

80. The promotional materials that were discontinued included but were not limited to product monographs that are the full prescribing information for the product, posters, and hospital displays.

81. In 2013, the FDA reviewed a professional direct mail piece for Benicar® and Benicar HCT® tablets submitted by Daiichi Sankyo. The FDA found the promotional material misleading because it made unsubstantiated efficacy

claims associated with Benicar® and Benicar HCT® in violation of the Federal Food, Drug and Cosmetic Act. Promotional materials are considered misleading if they represent or suggest that a drug is more effective than has been demonstrated by substantial evidence or substantial clinical experience.

82. The FDA requested that Daiichi Sankyo immediately cease the dissemination of violative promotional materials for Benicar and Benicar HCT.

83. Upon information and belief, the promotional activities described herein misled and deceived healthcare providers, including Plaintiffs' healthcare providers, and consumers, including Plaintiffs, to believe that Defendants' *olmesartan* products were safer and more effective than had been demonstrated. Consequently, neither healthcare providers nor consumers, including Plaintiffs, could conduct an adequate risk benefit analysis when determining whether to prescribe, purchase or use the drugs.

84. Upon information and belief, had Defendants not engaged in the unlawful promotional activities described herein, and if Defendants had accurately presented the safety and efficacy profiles of the *olmesartan* products in a fair and balanced way, Plaintiffs' healthcare providers would not have prescribed, and Plaintiffs would not have purchased or used, or would have discontinued the use of, the *olmesartan* products, and, therefore, Plaintiffs would not have suffered the damages complained of herein.

False Claims Act and Allegations Involving *Olmesartan* Products

85. On information and belief, on March 10, 2010, Kathy Fragoules of the State of Michigan ("Relator") filed a *qui tam* action in the United States District Court for the District of Massachusetts captioned *United States, et al., ex rel. Fragoules v. Daiichi Sankyo, Inc., et al.*, Civil Action No. 10.10420-NG, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 1320a-7b(b) (the "Civil Action"). In her complaint, Relator alleges, among other things, that Daiichi Sankyo U.S. caused false claims to be submitted to federal healthcare programs by providing inducements to physicians to prescribe Benicar®, Benicar HCT®, Welchol®, Azor® and Tribenzor® in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). These improper activities resulted in and/or contributed to physicians and health care providers prescribing the *olmesartan* products to the plaintiffs, and failing to properly and accurately evaluate the risk benefit profiles alone, and in comparison to alternative therapies, and, on information and belief, resulted in or contributed to the underreporting of adverse events.

86. On information and belief, in February 2011, Daiichi Sankyo, Inc. received an investigative subpoena *duces tecum* from the United States Department of Justice requesting a number of items including, but not limited to, documents evidencing or referring to the promotion, sales, marketing,

development, co- promotion or analysis of Benicar®, Benicar HCT®, and Azor®.

87. On information and belief, on May 5, 2011, Forest Labs received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking documents relating to the marketing of Benicar®, Benicar HCT® and Azor®.

88. On information and belief, in January 2012, Daiichi Sankyo U.S. received an administrative subpoena from the Office of the California Insurance Commissioner commanding the company to produce certain information, including payments made to promote the company's products in California and checks issued to physicians and/or professional corporations controlled by physicians for promotional programs promoting pharmaceutical products on behalf of Daiichi Sankyo U.S. The company was also asked to provide evidence of payments to physicians licensed to practice in California for participation in a speaker's bureau at which presentations were made regarding pharmaceutical products manufactured, developed and marketed by Daiichi Sankyo U.S., as well as any payments to physicians in California who attended speaker's bureau events.

89. On information and belief, the United States contended that it had certain civil claims against Daiichi Sankyo U.S. for having caused false claims to be submitted to Federal Healthcare Programs by paying kickbacks to induce

physicians to prescribe *olmesartan* products and Welchol. Specifically, the United States contends that the kickbacks took the form of honoraria payments, meals, and other remuneration to physicians who participated, or supposedly participated, in Physician Opinion & Discussion Programs ("PODs") during the period from January 1, 2005, through March 31, 2011, and other speaker programs during the period from January 1, 2004, through February 4, 2011 (collectively the "Speaker Programs").

90. On information and belief, the United States contended that the honoraria, meals and other remuneration detailed above were kickbacks, because Daiichi Sankyo U.S. paid physicians even when, among other things, the physician participants in PODs took turns "speaking" on duplicative topics over Daiichi-paid dinners, the recipient spoke only to members of his or her own staff in his or her own office, the audience included the honoraria's recipients or the associated dinner was so lavish that its cost exceeded Daiichi's own internal cost limitation of $140 per person.

91. In and around August of 2017, Defendants announced that they have agreed to enter into a program to settle ("Global Settlement"), on behalf of all defendants, pending product liability litigation against various Daiichi Sankyo and Forest entities. These cases are related to olmesartan products (Benicar, Benicar HCT, Azor and Tribenzor) and allegations that such products caused sprue-like

enteropathy and other severe gastro-intestinal symptoms. The settlement requires, among other thresholds, that at least 95 percent of all eligible litigants and claimants decide to opt-in to the settlement under certain conditions. Claimants eligible to opt-in to the settlement program, under certain conditions, include those with claims already filed in court.

Plaintiffs' History with the *Olmesartan* Product(s)

92. Plaintiffs who were prescribed Defendants' *olmesartan* products ingested and used them as directed according to their intended and directed use.

93. Plaintiffs were prescribed Defendants' *olmesartan* products primarily to treat hypertension.

94. Plaintiffs agreed to initiate treatment with Defendants' *olmesartan* products in an effort to reduce their blood pressure. Plaintiffs relied on claims made by Defendants that their *olmesartan* products were safe and effective for the treatment of hypertension.

95. After beginning treatment with Defendants' *olmesartan* products, Plaintiffs developed serious injuries.

96. At all times material hereto, Defendants knew or should have known that the risks associated with the use of their *olmesartan* products included the risk of developing the injuries alleged herein.

97. The development of Plaintiffs' injuries was preventable and resulted

directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life-threatening risks, deliberate, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of their *olmesartan* products. This conduct and the product defects complained of herein were substantial factors in bringing about and exacerbating Plaintiffs' injuries and a reasonably foreseeable consequence of Defendants' conduct and *olmesartan* products' defects.

98. At all times material hereto, Defendants, by and through their agents, servants and/or employees, negligently, recklessly and/or carelessly marketed, distributed and/or sold *olmesartan* products without adequate instructions or warning of their serious side effects and unreasonably dangerous risks.

99. Had Defendants properly disclosed the risks associated with their *olmesartan* products, Plaintiffs would have avoided the risk of developing the injuries complained of herein by not ingesting Defendants' *olmesartan* products and/or by discontinuing use when the injuries and sequalae resulted.

100. As a direct and proximate result of Defendants' negligence, wrongful conduct and the unreasonably dangerous and defective characteristics of its' *olmesartan* products, namely Benicar®, Benicar HCT®, Azor®, and Tribenzor®, Plaintiffs suffered severe and permanent physical and emotional

injuries, including those injuries complained of herein. Plaintiffs have endured pain and suffering, emotional distress, loss of enjoyment of life and economic loss, including incurring significant expenses for medical care and treatment which will continue in the future, and even death. Plaintiffs seek actual, compensatory, and punitive damages from Defendants.

101. Plaintiffs did not participate in the Global Settlement described above.

CLASS ACTION ALLEGATIONS

102. Plaintiffs bring this action as a class action under Title 12, Sections 2023(A) and 2023 (B) of Oklahoma Statutes, on behalf of themselves and the following Class:

> All citizens and entities that, during the relevant Class Period, purchased *olmesartan* from one or more of the Defendants, and suffered damages such as those alleged herein, but did not participate in the Global Settlement.

103. Plaintiffs do not know the exact number of members of Class because such information is in the exclusive control of Defendants. Due to the nature of the damages involved, Plaintiffs believe that the Class numbers are in the hundreds or thousands and therefore the Class is so numerous and geographically dispersed that joinder of all members is impracticable.

104. Plaintiffs' claims are typical of the claims of the other members of the Class. Plaintiffs and the members of the Class sustained damages arising out of

Defendants' common course of conduct in violation of law as alleged herein. The injuries and damages of each member of the Class were directly caused by Defendants' wrongful conduct.

105. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in prosecution of class action and antitrust litigation.

106. Common questions of law and fact exist as to all members of the Class, and predominate over any questions affecting solely individual members of the Class. These common questions include, but are not limited to:

a. Whether Benicar is toxic and unsafe;

b. Whether consumers who ingested Benicar are at increased risk of developing serious latent disease;

c. Whether in marketing and selling Benicar, Defendants failed to disclose the dangers and risks to the health of the consumers ingesting these drugs;

d. Whether Defendants failed to warn adequately of the adverse effects of Benicar;

e. Whether Defendants designed and manufactured an anti-hypertensive drug that was dangerously defective because its use leads to serious adverse health effects including, but not limited to, Olmesartan Associated Enteropathy ("OAE"), sprue-like enteropathy, villous atrophy/blunting/damage, inflammation, nausea, vomiting, chronic diarrhea, malnutrition, dehydration, atrophy, kidney failure, weight loss, abdominal and gastrointestinal pain, colitis, and/ or gastritis;

f. whether Defendants adequately tested its anti-hypertensive drug prior to

selling it;

g. whether the Defendants continued to label, manufacture, market, distribute, promote and sell its anti-hypertensive drug notwithstanding its knowledge of the dangerous nature of the anti-hypertensive drug; and

h. whether the information Defendants provided with its anti-hypertensive drug was adequate in warning of the potential hazards resulting from the use of the drug.

107. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The prosecution of separate actions by individual members of the Class would impose heavy burdens upon the courts and Defendants, and would create a risk of inconsistent adjudications of questions of law and fact common to the Class. A class action would achieve substantial economies of time, effort, and expense, and will ensure uniformity of decisions as to persons similarly situated. Plaintiffs do not anticipate any difficulty in the management of this action as a class action.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS AND OF REPOSE

108. Plaintiffs incorporate by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

109. Plaintiffs are within the applicable statutes of limitations for the claims presented herein because Plaintiffs did not discover the defects and unreasonably dangerous condition of Defendants' *olmesartan* products and risks

associated with their ingestion, and could not reasonably have discovered the defects and unreasonably dangerous condition of Defendants' *olmesartan* products and the risks associated with its ingestion, due to the Defendants' failure to warn, suppression of important information about the risks of the products, including but not limited to the true risk benefit profile, and the scope of side effects, injuries, and damages known by Defendants to result from the use of the *olmesartan* products, and other acts and omissions.

110. In addition, Defendants are estopped from relying on any statutes of limitations or repose by virtue of their acts of fraudulent concealment, affirmative misrepresentations and omissions, which include Defendants' intentional concealment from Plaintiffs, Plaintiffs' prescribing health care professionals and the general consuming public that Defendants' *olmesartan* products were defective, unreasonably dangerous and carried with them the serious risk of developing the injuries Plaintiffs have suffered while aggressively and continually marketing and promoting their *olmesartan* products as safe and effective for the treatment of hypertension. This includes, but is not limited to, Defendants' failure to disclose and warn of the gastrointestinal side effects and injuries known by Defendants to result from use of the *olmesartan* products, for example, and not by way of limitation, internal concern about reports of gastrointestinal and celiac-like symptoms, years before Defendants ever publicly

acknowledged or disclosed that the *olmesartan* products were thought or known to cause these injuries and their sequelae; suppression of information about these risks and injuries from physicians and patients, including Plaintiffs; use of sales and marketing documents and information that contained information contrary to the internally held knowledge regarding the aforesaid risks and injuries; and overstatement of the efficacy and safety of the *olmesartan* products.

111. Defendants had a duty to disclose that their *olmesartan* products were defective, unreasonably dangerous and that the ingestion of Defendants' *olmesartan* products carried with them the serious risk of developing the injuries Plaintiffs' have suffered. Defendants breached that duty.

112. Plaintiffs, Plaintiffs' prescribing health care professionals and the general consuming public, had no knowledge of, and no reasonable way of discovering, the defects found in Defendants' *olmesartan* products, their unreasonably dangerous condition or the true risks associated with their ingestion at the time they purchased and ingested Defendants' *olmesartan* products.

113. Defendants did not notify, inform, or disclose to Plaintiffs, Plaintiffs' prescribing health care professionals or the general consuming public that Defendants' *olmesartan* products were defective and that their ingestion carried with it the serious risk of developing the injuries Plaintiffs have suffered and complained of herein.

114. Because Defendants failed in their duty to notify Plaintiffs, Plaintiffs' prescribing health care professionals and the general consuming public that their *olmesartan* products were defective and, further, actively attempted to conceal this fact, Defendants should be estopped from asserting defenses based on statutes of limitation or repose.

115. Accordingly, Plaintiffs file these lawsuits within the applicable statutes of limitations, Plaintiffs could not by exercise of reasonable diligence have discovered any wrongdoing, nor could have discovered the causes of their injuries at an earlier time because some injuries occurred without initial perceptible trauma or harm, and when Plaintiffs' injuries were discovered, their causes were not immediately known or knowable based on the lack of necessary information, which was suppressed by the Defendants. Most, if not all, patients with *olmesartan*-related intestinal and colonic manifestations go for months or even years treating with multiple physicians, undergoing testing, being misdiagnosed, and receiving ineffective treatments before finally being properly diagnosed, if at all. Further, the relationship of Plaintiffs' injuries to *olmesartan* exposure through the Defendants' products was inherently difficult to discover, in part due to the Defendants' knowing suppression of important safety information. Consequently, the discovery rule should be applied to toll the running of the statutes of limitations until Plaintiffs discovered, or by the exercise

of reasonable diligence should have discovered, that Plaintiffs may have a basis for an actionable claim.

116. Plaintiffs discovered the Defendant's products were the cause of the injuries they suffered only after becoming aware of the existance of the Global Settlement, and related lawsuits, which provided the necessary information regarding the cause of their damages, which was suppressed by the Defendants.

COUNT I
Products Liability – Design Defect (Strict Liability)

117. Plaintiffs incorporate by reference each and every paragraph of this Petition as if fully set forth herein and further allege as follows.

118. At all times relevant to this action, the Defendants engaged in the business of selling, distributing, manufacturing, marketing, and promoting *olmesartan* products, which are defective and unreasonably dangerous to consumers, including Plaintiffs. These actions were under the ultimate control and supervision of Defendants Daiichi Sankyo and Forest.

119. At all times relevant to this action, the Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, distributed, or have recently acquired entities who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the *olmesartan* product(s) used by the Plaintiffs,

as described above. These actions are under the ultimate control and supervision of Defendants Daiichi Sankyo and Forest.

120. At all times relevant to this action, the Defendants expected their *olmesartan* products to reach and did reach the intended consumers, handlers, and persons coming into contact with these products throughout the United States, including the Plaintiffs, without substantial or material change in the way they were produced, manufactured, sold, distributed, labeled, and marketed by these Defendants. These actions are under the ultimate control and supervision of Defendants Daiichi Sankyo and Forest.

121. At all times relevant hereto, Defendants' *olmesartan* products were manufactured, designed and labeled in an unsafe, defective, and inherently dangerous manner which was dangerous for use by the public and, in particular, by the Plaintiffs.

122. At all times relevant to this action, the *olmesartan* products as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by the Defendants were defective in design and formulation, in one or more of the following particulars:

a. When placed in the stream of commerce, the drugs contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Plaintiffs to risks that exceeded the benefits of the drug;

b. When placed in the stream of commerce, they were defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the treatment of hypertension;

c. The drug(s) were insufficiently tested;

d. The drug caused(s) harmful side effects that outweighed any potential utility;

e. Defendants were aware at the time the *olmesartan* products were marketed that chronic, long-term intake of the *olmesartan* products would result in an increased risk of stomach, intestinal and/or colonic disease manifestations, chronic diarrhea, weight loss, hospitalization(s) related to dehydration and malnutrition, vomiting, and/or severe nausea;

f. Defendants were aware at the time that the drug was marketed that chronic, long-term use would result in causing an increased risk of bodily injuries;

g. Inadequate post-marketing surveillance; and/or

h. There were safer alternative designs and formulations that were not utilized.

123. Defendants' *olmesartan* products as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants were defective in design and formulation in that when they left the hands of the Defendants' manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with the design and formulation of Defendants' *olmesartan* products.

124. Defendants' *olmesartan* products, as researched, tested, developed,

designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants were defective in design and formulation in that when they left the hands of the Defendants' manufacturers and/or suppliers, they were unreasonably dangerous and were also more dangerous than the ordinary customer would expect.

125. At all times relevant to this action, the Defendants knew or had reason to know that the *olmesartan p*roducts were in a defective condition, and were inherently dangerous and unsafe when used in the manner instructed and provided by the Defendants.

126. With respect to products they manufactured or sold, Defendants had a duty to create products that were not unreasonably dangerous for their normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

127. Defendants marketed and promoted their *olmesartan* products as safe for treating hypertension. When Defendants placed their *olmesartan* products into the stream of commerce, they knew they would be prescribed to treat hypertension.

128. Plaintiffs were prescribed, purchased and used Defendants' *olmesartan* products. At the time of Plaintiffs' use/ingestion of Defendants' *olmesartan* products, the *olmesartan* products were being used for their intended

purpose and in a manner normally intended to treat hypertension.

129. Neither Plaintiffs nor Plaintiffs' health care professionals, by the exercise of reasonable care, could have reasonably discovered the defects and risks associated with Defendants' *olmesartan* products before Plaintiffs' ingestion of Defendants' *olmesartan* products.

130. The harm caused by Defendants' *olmesartan* products far outweighed their benefit, rendering Defendants' *olmesartan* products more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products. Defendants could have designed their *olmesartan* products to make them less dangerous. When Defendants designed their *olmesartan* products that caused Plaintiffs to develop serious injuries, the state of the industry's scientific knowledge was such that a less risky design was attainable.

131. At the time Defendants' *olmesartan* products left their control, there was a practical, technically feasible and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' *olmesartan* products. This was demonstrated by the existence of other hypertension medications which had a more established safety profile and a considerably lower risk profile.

132. Defendants' defective design of the *olmesartan* products was

willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of the *olmesartan* products. Defendants' conduct is motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of Defendants' *olmesartan* products.

133. The defects in Defendants' *olmesartan* products were substantial and contributing factors in causing Plaintiffs' injuries. But for Defendants' acts and omissions, Plaintiffs' would not have suffered the injuries complained of herein.

134. As a foreseeable, direct and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiffs were caused to suffer from the aforementioned injuries and damages.

135. Due to the unreasonably dangerous condition of Defendants' *olmesartan* products, Defendants are liable to Plaintiffs.

136. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with their *olmesartan* products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

137. As a proximate result of Defendants' wrongful acts and omissions,

Plaintiffs suffered severe and permanent physical and emotional injuries. Plaintiffs have endured pain and suffering, suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT II
Products Liability – Failure To Warn (Strict Liability)

138. Plaintiffs incorporate by reference each and every paragraph of this Petition as if fully set forth herein and further allege as follows.

139. Defendants have engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing *olmesartan* products and through that conduct have knowingly and intentionally placed their *olmesartan* products into the stream of commerce with full knowledge that it reaches consumers such as Plaintiffs who ingested them.

140. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the *olmesartan* products, in the course of same, directly advertised or marketed the products to the FDA, health care professionals, and consumers, including the Plaintiffs, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the *olmesartan* products.

141. Defendants expected that the *olmesartan* products they were selling, distributing, supplying, manufacturing and/or promoting to reach, and did in fact reach, prescribing health care professionals and consumers, including Plaintiffs and Plaintiffs' prescribing health care professionals, without any substantial change in the condition of the product from when they were initially distributed by Defendants. The *olmesartan* products manufactured and/or supplied by Defendants were defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or their health care professionals of such risks.

142. The *olmesartan* products were defective and unsafe such that they were unreasonably dangerous when they left the possession and/or control of

Defendants, were distributed by Defendants, and ingested by Plaintiffs in that the *olmesartan* products contained warnings insufficient to alert consumers, including the Plaintiffs herein, to the dangerous risks and reactions associated with the *olmesartan* products including the development of Plaintiffs' injuries.

143. This defect caused serious injury to Plaintiffs who used the *olmesartan* products for their intended purpose and in their foreseeable manner.

144. The Plaintiffs could not have discovered any defect in the *olmesartan* products through the exercise of reasonable care.

145. At all times herein mentioned, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings and take such steps to assure that the *olmesartan* products did not cause users to suffer from unreasonable and dangerous risks.

146. Defendants negligently and recklessly labeled, distributed, and promoted the aforesaid *olmesartan* products.

147. Defendants had a continuing duty to warn the Plaintiff of the dangers associated with the *olmesartan* products.

148. Defendants, as manufacturers, sellers, or distributors of prescription drugs, are held to the knowledge of an expert in the field.

149. Plaintiffs could not have discovered any defects in the *olmesartan*

products through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

150. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the facts that Defendants knew or should have known that their *olmesartan* products caused serious injuries, they failed to exercise reasonable care to warn of the dangerous risks associated with their use. The dangerous propensities of the *olmesartan* products, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

151. Each of the Defendants knew or should have known that the limited warnings disseminated with the use of the *olmesartan* products were inadequate, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug, in particular, failing to communicate to doctors warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for hypertension therapy.

152. Defendants communicated to health care professionals information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drug safely for use by patients for the purposes for which it is intended, including commonly employed long term antihypertensive drug therapy. In particular, the Defendants disseminated information that was inaccurate, false and misleading and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with such use of the *olmesartan* products; continued to aggressively promote the *olmesartan* products, even after it knew or should have known of the unreasonable risks from use; and overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any risks.

153. To this day, Defendants have failed to adequately and accurately warn of the true risks of Plaintiffs' injuries associated with the use of their *olmesartan* products.

154. Due to these deficiencies and inadequacies, the *olmesartan* products as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by the Defendants were unreasonably dangerous and defective.

155. Had Defendants properly disclosed and disseminated the risks associated with the *olmesartan* products, Plaintiffs would have avoided the risk

of developing injuries as alleged herein.

156. The Defendants that manufactured, sold, or distributed the *olmesartan* products that the Plaintiffs ingested are liable to Plaintiffs for injuries caused by the negligent or willful failure, as described above, to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of their respective product and the risks associated with its use.

157. As a proximate result of Defendants' wrongful acts and omissions, Plaintiffs suffered severe and permanent physical and emotional injuries. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT III
Gross Negligence

158. Plaintiffs incorporate by reference each and every paragraph of this

Petition as if fully set forth herein and further allege as follows.

159. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and the Plaintiffs for which the law would allow, and which Plaintiffs will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiffs; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs and their healthcare providers.

160. Plaintiffs relied on Defendants' representations and suffered injuries as a proximate result of this reliance.

161. Plaintiffs therefore assert claims for exemplary damages.

162. Plaintiffs also allege that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute

gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will seek exemplary damages in an amount that will punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT IV
Negligence

163. Plaintiffs incorporate by reference each and every paragraph of this Petition as if fully set forth herein and further allege as follows.

164. Defendants, directly or indirectly, caused the *olmesartan* products to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff.

165. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and/or distribution of the *olmesartan* products, including the duty to take all reasonable steps necessary to manufacture, promote and/or sell a product that

was not unreasonably dangerous to consumers and users of the product.

166. Defendants had a duty to exercise reasonable care in the marketing, advertising and sale of the *olmesartan* products, including a duty to warn Plaintiffs and other consumers of the dangers associated with the *olmesartan* products that were known or should have been known to Defendants at the time of the sale of the *olmesartan* products to Plaintiffs.

167. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of the *olmesartan* products increasing the risks of developing serious injuries.

168. Defendants had a duty to disclose to health care professionals the causal relationship or association of the *olmesartan* products to the development of Plaintiffs' injuries.

169. Defendants' duty of care owed to consumers, health care professionals, and patients included providing accurate, true and correct information concerning: (1) the clinical safety and effectiveness profiles of *olmesartan* products, and (2) appropriate, complete, and accurate warnings concerning the adverse effects of the *olmesartan* products, including Plaintiffs' injuries.

170. During the time that Defendants designed, manufactured, packaged,

labeled, promoted, distributed and/or sold the *olmesartan* products, Defendants knew, or in the exercise of reasonable care should have known, that their products were defective, dangerous, and otherwise harmful to Plaintiffs.

171. Defendants knew, or in the exercise of reasonable care should have known, that the use of the *olmesartan* products could cause or be associated with Plaintiffs' injuries and thus created a dangerous and unreasonable risk of injury to users of the products.

172. Defendants knew from their own investigations, including analysis of sales statistics, adverse event reporting, and/or scientific studies published in peer- reviewed medical journals, that many health care professionals were unaware of the extent of these risks posed by the *olmesartan* products.

173. Defendants knew that many health care professionals were prescribing the *olmesartan* products, and that many patients developed serious side effects including but not limited to stomach, intestinal, and/or colonic disease manifestations, chronic diarrhea, weight loss, vomiting, nausea, dehydration, and malnutrition.

174. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, marketing, advertisement, packaging, sale, testing, quality assurance, quality control, sale, and distribution of the

olmesartan products in interstate commerce, in that Defendants knew and had reason to know that a consumer patient's use and ingestion of the product(s) created a significant risk of suffering unreasonably dangerous health related side effects, including Plaintiffs' injuries, and failed to prevent or adequately warn of these risks and injuries.

175. Defendants were further negligent in that they manufactured and produced defective products containing the drug *olmesartan medoxomil*, knew and were aware of the defects inherent in the products, failed to act in a reasonably prudent manner in designing, testing, and marketing the products, and failed to provide adequate warnings of the products' defects and risks.

176. Defendants were further negligent and breached their continuing duty of pharmacovigilance with respect to Plaintiffs. Defendants, through clinical trials and other adverse event reports, learned that there were serious problems with the *olmesartan* products' use and failed to inform physicians, regulatory agencies, and the public of this risk. Defendants had the means and the resources to perform their pharmacovigilance duties for the entire time the *olmesartan* products have been on the market in the United States.

177. These physical injuries are severe in nature, including, but not limited to, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic illness

proximately caused by ingestion of the *olmesartan* product(s), the continued risk of requiring additional medical or surgical procedures including general anesthesia, with attendant risk of life-threatening complications.

178. Defendants' negligence included, but was not limited to, the following acts and omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling and/or distributing the *olmesartan* products without thorough and adequate pre- and post-market testing of the product;

b. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing the olmesartan products while negligently and/or intentionally concealing and failing to disclose the results of clinical trials and tests regarding use of the *olmesartan* products, which demonstrated the risk of serious harm associated with the use of *olmesartan* products;

c. Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of the *olmesartan* products;

d. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not the *olmesartan* products were safe for its intended use;

e. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew or had reason to know that the *olmesartan* products were indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users in the form of intestinal damage and other serious illnesses;

f. Failing to warn plaintiffs, health care professionals, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative antihypertensive medications available to plaintiffs and other consumers;

g. Declining to make or propose any changes to the *olmesartan* products' labeling or other promotional materials that would alert health care professionals to the risks of the *olmesartan* products;

h. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and consume the *olmesartan* products;

i. Advertising, marketing, and recommending the use of the *olmesartan* products, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected, associated or caused in the use of the *olmesartan* products;

j. Representing that the *olmesartan* products were safe for its intended use when in fact, Defendants knew or should have known that the products were not safe for their intended purpose;

k. Failing to advise health care professionals or patients taking the *olmesartan* products, that its statements regarding the safety of its products were inaccurate;

l. Failing to disclose to Plaintiffs and their health care professionals, through the prescribing information for the *olmesartan* products, about the risk of developing serious gastrointestinal injuries including stomach, intestinal, and colonic disease manifestations, including, but not limited to, *Olmesartan* Associated Enteropathy and/or lymphocytic colitis, microscopic colitis, and collagenous colitis, chronic diarrhea, weight

loss, nausea, vomiting, malnutrition, renal failure and/or dehydration;

m. Failing to disclose to and inform the health care professionals and consumers that other forms of safer and effective antihypertensive drugs were available for use to treat hypertension for which the *olmesartan* products were manufactured;

n. Failing to reference the chronic nature and severity of the adverse reactions associated with the drugs, including developing stomach, intestinal and colonic disease manifestations including but not limited to *Olmesartan* Associated Enteropathy and/or lymphocytic colitis, microscopic colitis, and collagenous colitis, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration;

o. Continuing to disseminate information to health care professionals which indicate or imply that the *olmesartan* products are not unsafe for treatment of hypertension;

p. Continuing the manufacture and sale of the *olmesartan* products with the knowledge that the products were unreasonably unsafe and dangerous, and failed to comply with FDA regulations and policy;

q. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the *olmesartan* products so as to avoid the risk of serious harm associated with the use of the *olmesartan* products as an antihypertensive medication;

r. Advertising, marketing, promoting and/or selling the *olmesartan* products for uses other than as approved and indicated in the product's label;

s. Failing to design and manufacture the *olmesartan* products so as to ensure the products were at least as safe and effective as other antihypertensive drugs on the market;

t. Failing to ensure the products were accompanied by proper and accurate warnings about the possible adverse side effects associated with the use of the *olmesartan* products and that use created a risk of stomach, intestinal and colonic disease manifestations, including, but not limited to, *Olmesartan* Associated Enteropathy and/or lymphocytic colitis, microscopic colitis, collagenous colitis, chronic diarrhea, weight loss, nausea, vomiting, malnutrition, and dehydration, that could be life-threatening; and/or

u. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of the *olmesartan* products.

179. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiffs would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution and sale of the *olmesartan* products.

180. Plaintiffs did not know the nature and extent of the injuries that could result from ingestion and use of the *olmesartan* product(s).

181. Defendants' negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiffs suffered, and will continue to suffer, as described and prayed for herein.

182. Defendants' conduct, as described above, was reckless. Defendants risk the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and suppressed this knowledge from the general public.

Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

183. As a proximate result of Defendants' wrongful acts and omissions, Plaintiffs suffered severe and permanent physical and emotional injuries. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT V

Negligence *per se* – Failure to Comply with FDA Regulations

184. Plaintiffs incorporate by reference each and every paragraph of this Petition as if fully set forth herein and further allege as follows.

185. Defendants have an obligation to not violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging,

supplying, marketing, selling, advertising, preparing for use, and warning of risks and dangers of the *olmesartan* products.

186. Upon information and belief, Defendants failed to comply with the FDA postmarketing reporting requirements under 21 C.F.R. § 314.80(c) by, *inter alia*, failing to report each adverse drug experience concerning the *olmesartan* products that is both serious and unexpected, including Plaintiffs' injuries complained of herein, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by Defendants, failing to promptly investigate all adverse drug experiences concerning the *olmesartan* products that are the subject of these postmarketing 15-day Alert reports, failing to submit follow up reports within 15 calendar days of receipt of new information or as requested by the FDA, and, if additional information is not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information. Defendants' failure to meet these requirements is evidence of defendants' negligence and constitutes negligence *per se*.

187. Consistent with 21 C.F.R. § 314.70 (c) (known as the "changes being effected" regulations), Defendants had and continue to have a duty to initiate a change to the *olmesartan* products' labels to reflect the true levels of risk, including the risk of developing Plaintiffs' injuries complained of herein.

To this day, Defendants have not adequately satisfied their duty to update the *olmesartan*products' prescribing information to reflect their knowledge as to the true risks of developing the injuries complained of herein. Defendants' failure to meet these regulatory requirements is evidence of defendants' negligence and constitutes negligence *per se*.

188. As a proximate result of Defendants' wrongful acts and omissions, Plaintiffs suffered severe and permanent physical and emotional injuries. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT VI
Negligent Misrepresentation

189. Plaintiffs incorporate by reference each and every paragraph of this Petition as if fully set forth herein and further allege as follows.

190. Defendants owed a duty in all of its undertakings, including th dissemination of information concerning the *olmesartan* products, to exercise reasonable care to ensure that it did not in those undertakings create unreasonable risks of personal injury to others.

191. Defendants disseminated to health care professionals and consumers through published labels, marketing materials and otherwise, information concerning the properties and effects of the *olmesartan* products with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe or ingest the *olmesartan* products.

192. Defendants, as drug designers, manufacturers, sellers, promoters and/or distributors, knew or should reasonably have known that health care professionals and consumers, in weighing the potential benefits and potential risks of prescribing or ingesting the *olmesartan* products, rely upon information disseminated and marketed to them regarding the products.

193. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of the *olmesartan* products were accurate, complete and not misleading and, as a result, disseminated information to health care professionals and consumers that was negligently and materially inaccurate,

misleading, false and unreasonably dangerous to consumers such as Plaintiffs.

194. Defendants, as designers, manufacturers, sellers, promoters and/or distributors, knew or reasonably should have known that patients receiving prescriptions for the *olmesartan* products, written by health care professionals in reliance upon information disseminated by Defendants as the manufacturer/distributor of the *olmesartan* products would be placed in peril of developing serious and potential life threatening injuries if the information disseminated and relied upon was materially inaccurate, misleading or otherwise false.

195. From the time the *olmesartan* products were first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety of the *olmesartan* products. Defendants made misrepresentations to Plaintiffs, Plaintiffs' health care professionals, and the general public, for example, failing to disclose the true extent of gastrointestinal and other injuries and symptoms known to result from use of the products. At all relevant times hereto, Defendants conducted sales and marketing campaigns to promote the sale of the *olmesartan* products and willfully deceived Plaintiffs, Plaintiffs' health care professionals, and the general public as to the health risks and consequences of the use of the *olmesartan* products.

196. Defendants made the foregoing representations without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representative and other authorized agents of Defendants, and in publications and other written materials directed to health care professionals, medical patients, and the public, with the intention of inducing reliance and the prescription, purchase, and use of the subject products.

197. Defendants had a duty to accurately and truthfully represent to medical professionals and U.S. consumers, including Plaintiffs, the truth regarding Defendants' claims that the *olmesartan* products had been tested and found to be safe and effective for hypertension treatment. The misrepresentations made by Defendants, in fact, were false and known by Defendants to be false at the time the misrepresentations were made by Defendants.

198. Defendants failed to exercise ordinary care in making their representations concerning the *olmesartan* products and their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce.

199. Defendants engaged in a campaign of over-promoting the *olmesartan* products in written marketing literature, in written product packaging, and in direct-to-consumer advertising via written and internet advertisements and

television commercial ads. Defendants' over-promotion was undertaken by touting the safety and efficacy of the *olmesartan* products while concealing, misrepresenting, actively downplaying the serious, severe, and life-threatening risks of harm to users of *olmesartan* products, when compared to comparable or superior alternative drug therapies Defendants negligently misrepresented the *olmesartan* products' risk of unreasonable, dangerous, adverse side effects.

200. Defendants' conduct, as described above, was reckless. Defendants risk the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspected public. Defendants' reckless conduct warrants an award of punitive damages.

201. As a proximate result of Defendants' wrongful acts and omissions, Plaintiffs suffered severe and permanent physical and emotional injuries. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together

with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT VII
Negligent Design

202. Plaintiffs incorporate by reference each and every paragraph of this Petition as if fully set forth herein and further allege as follows.

203. At all times relevant to this lawsuit, Defendants owed a duty to consumers, including Plaintiffs and their health care professionals, to exercise reasonable care in the design of the *olmesartan* products.

204. Defendants negligently and carelessly breached this duty of care to Plaintiffs because they designed the *olmesartan* products which:

a. were and are unreasonably defective in design because *olmesartan* products unreasonably increased the risks of developing Plaintiffs' injuries complained of herein;

b. were and are defective in design and were not reasonably safe as intended to be used;

c. were and are defective in design, making use of the *olmesartan* products more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with like products;

d. were and are defective in that they contained insufficient, incorrect and defective warnings in that they failed to alert health care

professionals and users, including Plaintiffs, of the risks of adverse effects;

e. were and are defective in design in that the *olmesartan* products were not safe for their intended use and were inadequately tested;

f. were and are defective in design because the *olmesartan* products' risks exceeded any benefit of the drugs;

g. failed to act as a reasonable and prudent manufacturer, seller, promoter, distributor or marketer would have acted with respect to the design of the *olmesartan* products; and/or

h. defective in design because the design did not include an adequate study and testing regimen, particularly in the post-marketing period;

205. Defendants' *olmesartan* products were expected to, and did, reach the intended consumers, handlers and persons coming into contact with the products without substantial change in the condition in which they were researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants.

206. At all times relevant hereto, Defendants' *olmesartan* products were manufactured, designed and labeled in an unsafe, defective and inherently dangerous condition which was dangerous for use by the public and in particular by Plaintiffs.

207. Defendants had a duty to create a product that was not

unreasonably dangerous for its normal, common intended use.

208. At the time of Plaintiffs' use of Defendants' *olmesartan* products, they were being used for their intended purposes and in a manner normally intended, to primarily treat hypertension.

209. The harm caused by Defendants' *olmesartan* products far outweighed their benefits, rendering the *olmesartan* products more dangerous and less effective than an ordinary consumer or health care professionals would expect and more dangerous than alternative products. Defendants could have designed their *olmesartan* products to make them less dangerous. When Defendants manufactured the *olmesartan* products that caused Plaintiffs to develop Plaintiffs' injures, the state of the industry's scientific knowledge was such that a less risky design was attainable.

210. At the time Defendants' products left their control, there was a practical, technically feasible and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the *olmesartan* products. This was demonstrated by the existence of other hypertension medications which had a more established safety profile and a considerably lower risk profile.

211. Plaintiffs could not, in the reasonable exercise of care, have discovered the defects of the *olmesartan* products and perceived their danger.

212. The defects in Defendants' product were substantial contributing factors in causing Plaintiffs' injuries. But for Defendants' acts and omissions Plaintiffs would not have suffered the injuries complained of herein.

213. As a proximate result of Defendants' wrongful acts and omissions, Plaintiffs suffered severe and permanent physical and emotional injuries. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT VIII
Fraudulent Concealment

214. Plaintiffs incorporate by reference each and every paragraph of this Petition as if fully set forth herein and further allege as follows.

215. Throughout the relevant time period, Defendants knew that the *olmesartan* products were defective and unreasonably unsafe for their intended

purpose, and intentionally and willfully, failed to disclose and suppressed this information and the true nature of the risks of use of the *olmesartan* products. This includes, but is not limited to, Defendants' failure to disclose and warn of the gastrointestinal side effects and injuries, including Plaintiffs' injuries, known by Defendants to result from use of the *olmesartan* products, for example, and not by way of limitation, internal concern about reports of gastrointestinal and celiac-like symptoms, years before Defendants ever publicly acknowledged or disclosed that the *olmesartan* products were thought or known to cause these injuries and their sequelae; suppression of information about these risks and injuries from physicians and patients, including Plaintiffs; use of sales and marketing documents and information that contained information contrary to the internally held knowledge regarding the aforesaid risks and injuries; and overstatement of the efficacy and safety of the *olmesartan* products.

216. Defendants fraudulently concealed from or failed to disclose to or warn Plaintiffs and health care professionals that the *olmesartan* products were defective, unsafe, unfit for the purposes intended, and that they were not of merchantable quality.

217. Defendants were under a duty to Plaintiffs to disclose and warn of the defective and dangerous nature of the *olmesartan* products because:

a. Defendants were in a superior position to know the true quality, safety

and efficacy of the *olmesartan* products;

b. Defendants knowingly made false claims about and omitted important information about the safety and quality of the *olmesartan* products in the documents and marketing materials Defendants provided to physicians and the general public; and

218. Defendants fraudulently and affirmatively concealed and omitted to disclose the defective and dangerous nature of the *olmesartan* products from Plaintiffs. The facts concealed or not disclosed by Defendants to Plaintiffs were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or use the *olmesartan* products.

219. Defendants intentionally concealed or failed to disclose the true defective nature of the *olmesartan* products so that Plaintiffs would request and purchase the *olmesartan* products, and that their health care providers would dispense, prescribe, and recommend the *olmesartan* products, and Plaintiffs justifiably acted or relied upon, to their detriment, the concealed or non-disclosed facts as evidenced by their purchase of the *olmesartan* products.

220. Defendants, by concealment or other action, intentionally prevented Plaintiffs and Plaintiffs' health care professionals from acquiring material information regarding the lack of safety of the *olmesartan* products, and are subject to the same liability to Plaintiffs for Plaintiffs' losses, as though Defendants had stated the non-existence of such material information regarding

the *olmesartan* products' lack of safety and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that Plaintiffs were thus prevented from discovering the truth. Defendants therefore have liability for fraudulent concealment under all applicable law, including, *inter alia*, Restatement (Second) of Torts § 550 (1977).

221. As a proximate result of Defendants' wrongful acts and omissions, Plaintiffs suffered severe and permanent physical and emotional injuries. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual, compensatory and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT IX
Breach of Express Warranties

222. Plaintiffs incorporate by reference each and every paragraph of this Petition as if fully set forth herein and further allege as follows.

223. At all times material hereto, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing the *olmesartan* products, which are unreasonably dangerous and defective, thereby placing the *olmesartan* products into the stream of commerce.

224. At all times mentioned, Defendants expressly represented and warranted to Plaintiffs and Plaintiffs' prescribing health care professionals, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for health care professionals, medical patients, Plaintiffs and the general public, that the *olmesartan* products were safe, effective, fit and proper for their intended use. These express representations include incomplete prescribing information which purports, but fails, to include the true risks associated with use of the *olmesartan* products. In fact, Defendants knew or should have known that the risks expressly included in the *olmesartan* products' prescribing information, including package inserts, did not and do not accurately or adequately set forth the true risks of developing the serious injuries complained of herein. Despite this, Defendants expressly warranted the *olmesartan* products as safe and effective for use. Healthcare providers, including Plaintiffs' healthcare providers, and consumers, including Plaintiffs,

prescribed, purchased and used the *olmesartan* products relying upon these warranties.

225. Defendants advertised, labeled, marketed, and promoted the *olmesartan* products, representing the quality to health care professionals, Plaintiffs, and the public in such a way as to induce their purchase or use, thereby making an express warranty that the *olmesartan* products would conform to the representations. More specifically, the prescribing information for the *olmesartan* products did not and does not contain adequate information about the true risks of developing the injuries complained of herein. Despite this, Defendants expressly represented that the *olmesartan* products were safe and effective, that they were safe and effective for use by individuals such as Plaintiffs, and/or that they were safe and effective to treat Plaintiffs' conditions. Portions of the prescribing information, relied upon by Plaintiffs and their health care professionals, including, but not limited to, the "Warnings and Precautions" section, purport to expressly include the risks associated with the use of the *olmesartan* products, but those risks are neither accurately nor adequately set forth.

226. The representations about the *olmesartan* products, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis

of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

227. Defendants breached said warranties in that the *olmesartan* products were defective, dangerous, unfit for use, did not contain the true and adequate nature of the risks associated with their use, and were not merchantable and not safe for their intended, ordinary and foreseeable use and purpose.

228. Defendants placed the *olmesartan* products into the stream of commerce for sale and recommended their use to health care professionals, Plaintiffs, and consumers without adequately warning of the true risks of developing the injuries complained of herein being associated with the use of the *olmesartan* products.

229. Defendants had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale and release of the *olmesartan* products, including a duty to:

a. Ensure that the product did not cause the user unreasonably dangerous side effects;

b. Warn of dangerous and potentially fatal side effects; and

c. Disclose adverse material facts, such as the true risks associated with the use of the *olmesartan* products, when making representations to health care professionals, including Plaintiffs' healthcare providers, and the public at large, including Plaintiffs.

230. Defendants breached these express warranties with respect to the *olmesartan* products, including the following particulars:

231. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the *olmesartan* products were safe, and fraudulently withheld and concealed information about the true risks of serious injury or death associated with using the *olmesartan* products by expressly limiting the risks associated with use within the prescribing information;

232. Defendants represented that the *olmesartan* products were safe, or safer than other alternative medications, and fraudulently concealed information which demonstrated that the *olmesartan* products were not safer than alternatives available on the market; and

233. Defendants, through advertising and promotional materials and the statements of sales representatives and paid endorsers, expressly warranted that the *olmesartan* products were safe and expressly and intentionally limited the risks disclosed within the prescribing information.

234. When Plaintiffs' health care professionals prescribed the *olmesartan* product(s) and Plaintiffs made the decision to use the drug, both reasonably relied upon the Defendants and their agents to disclose known defects, risks, dangers,

and side effects of the *olmesartan* products.

235. Plaintiffs' prescribing health care professionals and the Plaintiffs had no knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning the *olmesartan* products when prescribed or otherwise provided the *olmesartan* products, and Plaintiffs purchased and used the *olmesartan* products as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted, sold or otherwise released into the stream of commerce by the Defendants.

236. Upon information and belief, Plaintiffs and/or their prescribing health care professionals were at all relevant times in privity with Defendants.

237. Plaintiffs justifiably and detrimentally relied on the express warranties and representations of Defendants in the purchase and use of the *olmesartan* products.

238. Defendants had sole access to material facts concerning the incomplete and inaccurate nature of the risks associated with the *olmesartan* products as expressly stated within the prescribing information, and Defendants knew that health care professionals, such as Plaintiffs' healthcare professionals, and users such as Plaintiffs, could not have reasonably discovered that the risks expressly included in the prescribing information were both inadequate and inaccurate.

239. Further, given the serious risks associated with Defendants' *olmesartan* products, a reasonable manufacturer with Defendants' knowledge of these risks would not have sold, marketed, promoted and/or distributed the products in the same condition as Defendants sold, marketed, promoted and/or distributed their products to the public, including to Plaintiffs.

240. Had the prescribing information for the *olmesartan* products accurately and adequately set forth the true risks associated with the use of such products, including Plaintiffs' injuries, rather than expressly excluding such information and warranting that the products were safe for their intended use, Plaintiffs could have avoided the injuries complained of herein.

241. As a direct and proximate result of Defendants' conduct as aforesaid, Plaintiffs suffered past and future personal injuries and losses.

242. The injuries and losses suffered by Plaintiffs are a direct and proximate result of the negligence and carelessness of the Defendants and are not due to any act or failure to act on the part of the Plaintiffs.

243. As a proximate result of Defendants' wrongful acts and omissions Plaintiffs suffered severe and permanent physical and emotional injuries. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and

punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT X
Breach of Implied Warranties

244. Plaintiffs incorporate by reference each and every paragraph of this Petition as if fully set forth herein and further allege as follows.

245. At all relevant times in this action, Defendants manufactured, distributed, sold, advertised, promoted, and sold the *olmesartan* products.

246. Prior to the time that the aforementioned products were used by Plaintiffs, Defendants impliedly warranted to Plaintiffs and Plaintiffs' agents and health care professionals that the *olmesartan* products were of merchantable quality and safe and fit for the use for which they were intended.

247. Specifically, Defendants impliedly warranted to Plaintiffs that their products were intended to treat hypertension and were safe and fit for that use, but Defendants failed to disclose that the use of their *olmesartan* products carried with them an increased risk of developing Plaintiffs' injuries.

248. The *olmesartan* products were neither safe for their intended use nor of merchantable quality, as impliedly warranted by Defendants, in that the *olmesartan* products have dangerous propensities when used as intended and can cause serious injuries, including, but not limited to those injuries complained of herein.

249. At all relevant times, Defendants intended that the *olmesartan* products be used in the manner that Plaintiffs in fact used them and Defendants impliedly warranted each product to be of merchantable quality, safe, and fit for such use, despite the fact that the *olmesartan* products were not adequately tested.

250. Defendants were aware that consumers, including Plaintiffs, would use the *olmesartan* products as marketed by Defendants, which is to say that Plaintiffs were foreseeable users of the *olmesartan* products.

251. Upon information and belief, Plaintiffs and/or their health care professionals were at all relevant times in privity with Defendants.

252. The *olmesartan* products were expected to reach and did in fact reach consumers, including Plaintiffs, without substantial change in the condition in which they were manufactured and sold by Defendants.

253. Defendants' *olmesartan* products were dangerous and defective when Defendants placed them into the stream of commerce because of their

propensity to cause Plaintiffs' injuries.

254. In reliance upon Defendants' implied warranty, Plaintiffs used the *olmesartan* products as prescribed and in the foreseeable manner normally intended, recommended, promoted and marketed by Defendants.

255. Plaintiffs, individually and through their prescribing health care professionals, reasonably relied upon the skill, superior knowledge and judgment of Defendants and upon the implied warranties that the *olmesartan* products were of merchantable quality and fit for their intended purpose or use.

256. Defendants breached their implied warranty to Plaintiffs in that the *olmesartan* products were not of merchantable quality, safe or fit for their intended use, or adequately tested, in violation of applicable laws.

257. Defendants breached the warranties of merchantability and fitness for its particular purpose because the *olmesartan* products were unduly dangerous and caused undue injuries, including, but not limited to, Plaintiffs' injuries.

258. The harm caused by Defendants' *olmesartan* products far outweighed their benefit, rendering the *olmesartan* products more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products.

259. Neither Plaintiffs nor Plaintiffs' health care professionals could have reasonably discovered or known of the risk of serious injury and/or death

associated with Defendants' *olmesartan* products.

260. Defendants' breaches of implied warranties caused Plaintiffs' injuries.

261. As a direct and proximate result of Defendants' wrongful acts and omissions Plaintiffs suffered severe and permanent physical and emotional injuries. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT XI
Unjust Enrichment

262. Plaintiffs incorporate by reference each and every paragraph of this Petition as if fully set forth herein and further allege as follows.

263. Plaintiffs conferred a benefit on Defendants by purchasing Defendants' *olmesartan* products.

264. Plaintiffs, however, did not receive the safe and effective drug for

which Plaintiffs paid.

265. In exchange for the payments made for *olmesartan* products, and at the time payments were made, Plaintiffs expected that Defendants' *olmesartan* products were safe and medically effective for the treatment of the condition, illness, disorder or symptom for which they were prescribed.

266. Defendants have voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiffs paid for the *olmesartan* products when they otherwise would not have done so. The failure of Defendants to provide Plaintiffs with the remuneration expected enriched Defendants unjustly.

267. It would be inequitable for Defendants to retain this money because Plaintiffs did not, in fact, receive a safe and efficacious drug.

268. By virtue of the conscious wrongdoing alleged in this Master Long Form Complaint, Defendants have been unjustly enriched at the expense of Plaintiffs who hereby seek the disgorgement and restitution of Defendants' wrongful profits, revenue and benefits to the extent and in the amount deemed appropriate by the Court and for such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

269. As a direct and proximate result of Defendants' wrongful acts and omissions Plaintiffs suffered severe and permanent physical and emotional

injuries. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT XII
Violation of Consumer Protection Laws

270. Plaintiffs incorporate by reference each and every paragraph of this Petition as if fully set forth herein and further allege as follows.

271. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or have made false representations in violation of Okla. Stat. Ann. Tit. 15, §§751 et. seq.

272. The actions and failure to act of Defendants, including the false and misleading representations and omissions of material facts regarding the safety and potential risks of Defendants' *olmesartan* products and the above described course of fraudulent conduct and fraudulent concealment constitute acts, uses or

employment by Defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression or omission of material facts in connection with the sale of merchandise of Defendants in violation of the consumer protection statutes listed above.

273. By reason of the unlawful acts engaged in by Defendants, Plaintiffs have suffered ascertainable loss and damages.

274. As a direct and proximate result of Defendants' conduct, Plaintiffs suffered and will continue to suffer personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

COUNT XIII
Punitive Damages

275. Plaintiffs incorporate by reference each and every paragraph of this

Petition as if fully set forth herein and further allege as follows.

276. Plaintiffs are entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiffs, by making intentionally false and fraudulent misrepresentations about the safety of the *olmesartan* products. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of the *olmesartan* products, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting the *olmesartan* products, despite Defendants' knowledge and awareness of the serious side effects and risks associated with the *olmesartan* products.

277. Defendants had knowledge of, and were in possession of evidence demonstrating that the *olmesartan* products caused serious side effects. Notwithstanding Defendants' knowledge of the serious side effects of the *olmesartan* products, Defendants continued to market the drug products by providing false and misleading information with regard to the product's safety to the regulatory agencies, the medical community, and consumers of the

olmesartan products.

278. Although Defendants knew or recklessly disregarded the fact that the *olmesartan* products cause debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute the *olmesartan* products to consumers, including Plaintiffs, without disclosing these side effects when there were safer alternative methods for treating hypertension.

279. Defendants failed to provide warnings that would have dissuaded health care professionals from prescribing the *olmesartan* products and consumers from purchasing and ingesting the *olmesartan* products, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing or consuming the *olmesartan* products.

280. Defendants knew of the *olmesartan* products' defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell and/or promote the drug as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs in a conscious or negligent disregard of the foreseeable harm caused by the *olmesartan* products.

281. The acts, conduct, and omissions of Defendants, as alleged throughout this Master Complaint were willful and malicious. Defendants committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Plaintiffs and other *olmesartan* product users and for

the primary purpose of increasing Defendants' profits from the sale and distribution of the *olmesartan* products. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example out of Defendants.

282. Prior to the manufacturing, sale, and distribution of the *olmesartan* products, Defendants knew that said drugs were in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the drugs presented a substantial and unreasonable risk of harm to the public, including Plaintiffs and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using the *olmesartan* products.

283. Despite their knowledge, Defendants, acting through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in the *olmesartan* products and failed to warn the public, including Plaintiffs, of the extreme risk of injury occasioned by said defects inherent in *olmesartan* products. Defendants and their agents, officers, and directors intentionally proceeded with the

manufacturing, sale, and distribution and marketing of the *olmesartan* products knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

284. Defendants' conduct was despicable and so contemptible that they would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiffs, entitling Plaintiffs to exemplary damages.

WHEREFORE, Plaintiffs demand judgment in his favor and against the above-named Defendants, jointly and severally, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray:

A. That the Court determine that this action may be maintained as a class action under Title 12, Sections 2023(A) and 2023(B) of Oklahoma Statutes;

B. That the Court, pursuant to Title 12, Section 2023(C) of Oklahoma Statutes, set a hearing date as soon as practicable, to hear evidence and enter an order certifying this action as a class action, defining

the class and class claims, issues or defenses, and appointing class counsel.

C. That Defendants and all other persons or entities acting or claiming to act on their behalf be permanently enjoined and restrained from continuing and maintaining the conspiracy alleged in this Petition;

D. That the Court award Plaintiffs and the Class attorneys' fees and costs as well as pre-judgment and post-judgment interest permitted by law;

E. That the Court award Plaintiffs and the Class punitive damages in the amount determined by the jury; and

F. That the Court award Plaintiffs and the Class such other and further relief as may be deemed just and appropriate.

JURY DEMAND

Plaintiff hereby demands a trial by jury in this case as to such issues so triable.

Respectfully Submitted:

FULMER SILL

By: /s/ Matthew J. Sill
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ATTORNEY LIEN CLAIMED

Exhibit 1

Exhibit A

PLAINTIFF ADDRESSES

TRACY HANDLEY
8133 NW 28th Terrace, Bethany, OK 73008

SHELLY PHILLIPS
2809 NW 57th Street, Oklahoma City, OK 73112

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104 Warwick St., Park Forest, IL 60466

JANICE ATWELL
20700 NE Magnolia St., Blountstown, FL 32424

ERNEST HOPKINS
2251 Holben Rd.
Crescent City, CA 95531

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334 Glendale Ave., Norfolk, VA 23505

BRETT RICH
117 Dunbar Ave., Dunbar, WV 25064

SANDEE SALMON
47 Cody Cove, Iuka, MS 38852

Exhibit 1

Exhibit B

DEFENDANT ADDRESSES

DAIICHI SANKYO, INC.
Two Hilton Court, Parsippany, New Jersey 07054

DAIICHI SANKYO CO., LTD.
3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan

DAIICHI SANKYO U.S. HOLDINGS, INC.
Two Hilton Court, Parsippany, New Jersey 07054

FOREST LABORATORIES, LLC
Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054

FOREST LABORATORIES, INC.
909 Third Avenue, New York, New York 10022

FOREST PHARMACEUTICALS, INC.
13600 Shoreline Drive, St. Louis, Missouri

FOREST RESEARCH INSTITUTE, INC.
Harborside Financial Center, Plaza V, Suite 1900, Jersey City, New Jersey

Exhibit 1